

Message

From: Bussard, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF26B876393E44F38BDD06DB02DBBFE5-BUSSARD, DAVID]
Sent: 4/9/2018 6:53:46 PM
To: Kraft, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a94a4f199b247778abb02285a51b927-Kraft, Andrew]; Glenn, Barbara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a2dc9210d2d4d02a623b33f87f49436-Glenn, Barbara]; Ramasamy, Santhini [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f078b65256de4c22a8ec9d9f9720715f-SRAMASAM]
Subject: Fwd: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Resending. I meant to send to all three of you.

David Bussard

Begin forwarded message:

From: "Bussard, David" <Bussard.David@epa.gov>
Date: April 9, 2018 at 2:53:03 PM EDT
To: "Kraft, Andrew" <Kraft.Andrew@epa.gov>
Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Deliberative Process / Ex. 5

David Bussard

On Apr 9, 2018, at 1:14 PM, Kraft, Andrew <Kraft.Andrew@epa.gov> wrote:

From: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>
Sent: Monday, April 9, 2018 8:19 AM
To: Glenn, Barbara; Kraft, Andrew
Cc: Theo Vermeire; Paul Janssen; Joke Herremans; Els Smit
Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Barbara and Andrew,

Thank you for your answer!

10th of May, 9:00 EDT (15:00 CET) is also the best time for us. I will send you the invitation today.

Could you, please, supply the specific points you would like to discuss; our main issues you can find in the mail from 11/22/2017 (below). I would like to prepare a preliminary agenda for this TC; you will get this ASAP for comments and additions.

Kind regards

Lidka

Lidka Maslankiewicz
National Institute for Public Health and the Environment (RIVM)
Centre for Safety of Substances and Products
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Postbus 1 | 3720 BA Bilthoven
tel. 31 (0)30 2743160
+31 6 46 86 07 73
fax. 31 (0)30 2744401
e-mail: Lidka.Maslankiewicz@rivm.nl

From: "Glenn, Barbara" <Glenn.Barbara@epa.gov>
To: "Kraft, Andrew" <Kraft.Andrew@epa.gov>, Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>,
Cc: Theo Vermeire <theo.vermeire@rivm.nl>, Paul Janssen <paul.janssen@rivm.nl>, Joke Herremans <joke.herremans@rivm.nl>, Els Smit <els.smit@rivm.nl>
Date: 04/09/2018 02:03 PM
Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Hello,

I'm available on the 10th and possibly April 19th. May 10th may be best because there may be others interested from here.

Thanks for getting in touch with us.

Regards, Barbara

From: Kraft, Andrew

Sent: Monday, April 09, 2018 7:53 AM

To: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>; Glenn, Barbara <Glenn.Barbara@epa.gov>

Cc: Theo Vermeire <theo.vermeire@rivm.nl>; Paul Janssen <paul.janssen@rivm.nl>; Joke Herremans <joke.herremans@rivm.nl>; Els Smit <els.smit@rivm.nl>

Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Hi Lidka,

Good to hear from you. We are still interested in having a discussion.

Of the times you proposed, the only one I currently have available is May 10th. If that does not work for someone else, I can probably move something to make April 19th work. The other 2 times are probably not possible.

I look forward to our discussion.

-Andrew

From: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>
Sent: Monday, April 9, 2018 4:50 AM
To: Glenn, Barbara; Kraft, Andrew
Cc: Theo Vermeire; Paul Janssen; Joke Herremans; Els Smit
Subject: Fw: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Barbara and Andrew,

Please, let us know if you are still interested in the discussion on formaldehyde assessment. The topics mentioned in our previous mail are still of interest for us.

We would like to propose the following dates and times for a telephone conference:

12th and 19th of April 2018, 9 – 10 am EST (15:00 – 16:00 our time), or

2nd and 10th of May 2018, 9 – 10 am EST (15:00 – 16:00 our time).

If you prefer different dates or times, please, let us know.

We hope to hear from you soon.

Kind regards

Lidka

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----- Forwarded by Lidka Maslankiewicz/RIVM/NL on 04/09/2018 10:48 AM -----

From: Lidka Maslankiewicz/RIVM/NL
To: "Glenn, Barbara" <Glenn.Barbara@epa.gov>,
Cc: "Bussard, David" <Bussard.David@epa.gov>, "D'Amico, Louis" <DAmico.Louis@epa.gov>, Els Smit <els.smit@rivm.nl>, Joke Herremans <joke.herremans@rivm.nl>, "Kraft, Andrew" <Kraft.Andrew@epa.gov>, Paul Janssen <paul.janssen@rivm.nl>, "Thayer, Kris" <thayer.kris@epa.gov>, Theo Vermeire <theo.vermeire@rivm.nl>
Date: 11/22/2017 04:32 PM
Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Barbara and Andrew,

It is our turn to apologize for a delay.

Yes, we would be very interested to talk about the formaldehyde assessment and its methods for quantification of cancer risk for NPC. As I have already informed you, we are currently in the process of updating our national air limit for this chemical and we would like to use the data as presented in the 2010 draft, more specifically the quantification of cancer risks for NPC (Nasopharyngeal Cancer), based either on human data and on animal data as presented in this Draft.

We would appreciate the opportunity to discuss the current status of the IRIS Toxicological Review of Formaldehyde.

We are also interested if there is any possibility to use the data (especially derived inhalation cancer unit risk for NPC (Nasopharyngeal Cancer)), without referring as to an official EPA position, but rather a scientific approach.

We have noted that in 2014 US-EPA convened a workshop (https://www.epa.gov/sites/production/files/2014-12/documents/formaldehyde_workshop_agenda_final.pdf), the topics of which were the endogenous formation of formaldehyde and its relation to formaldehyde toxicity and the mechanistic evidence for lymphohematopoietic cancer induction by formaldehyde. Any further information on these topics and on the envisaged timeline for finalization of the US-EPA IRIS evaluation would be very welcome.

April 30th to May 1st, 2014 Crystal City Marriott at ...

www.epa.gov

Luoping Zhang, University of California at Berkeley, discussant Robert Snyder, Rutgers University (retired), discussant Martha Sandy, California EPA, discussant

We also would like to know, how will US-EPA react to the comments of NAS (especially their comments on the calculation of the unit risks)? Moreover, will the unit risk calculation change in the near future?

Here are several dates we would like to propose:

13th, 20th, 21st or 22nd of December 2017, 9 – 10 am EST (15:00 – 16:00 our time), or

17th, 18th, 24th or 25th of January 2018, 9 – 10 am EST (15:00 – 16:00 our time).

We hope to hear from you soon.

Kind regards

Lidka

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From: "Glenn, Barbara" <Glenn.Barbara@epa.gov>
To: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>, "Kraft, Andrew" <Kraft.Andrew@epa.gov>,
Cc: "Bussard, David" <Bussard.David@epa.gov>, "D'Amico, Louis" <DAmico.Louis@epa.gov>, Els Smit
<els.smit@rivm.nl>, Joke Herremans <joke.herremans@rivm.nl>, Paul Janssen <paul.janssen@rivm.nl>, "Thayer,
Kris" <thayer.kris@epa.gov>, Theo Vermeire <theo.vermeire@rivm.nl>
Date: 10/10/2017 04:48 PM
Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Lidka,

We would like to schedule a time to talk about the formaldehyde assessment and its methods for quantification of cancer risk for NPC. It would be great to explore what might be possible. I have some proposed dates and times for you to select from. Will this be possible for you?

Oct. 30 9 – 10 am EST

Nov 1 9 – 10 am EST

Nov 7 9 – 10 am EST

Thank you very much for your patience with our process and timing. Regards, Barbara and Andrew

From: Lidka Maslankiewicz [<mailto:lidka.maslankiewicz@rivm.nl>]
Sent: Friday, September 22, 2017 4:54 AM
To: Kraft, Andrew <Kraft.Andrew@epa.gov>
Cc: Bussard, David <Bussard.David@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Els Smit <els.smit@rivm.nl>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Joke Herremans <joke.herremans@rivm.nl>; Paul Janssen <paul.janssen@rivm.nl>; Thayer, Kris <thayer.kris@epa.gov>; Theo Vermeire <theo.vermeire@rivm.nl>
Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Andrew and Barbara

Thank you for your reply, apologies for not answering sooner.

The issue is that we would like to use the data as presented in the 2010 Draft, more specifically the quantification of cancer risks for NPC (Nasopharyngeal Cancer), based either on human data and on animal data.

From your mail, we understand that the information is not to be cited as the EPA position. That was not our intention, but rather we want to include the unit risks as a scientific approach that has been developed and that we need to take on board.

Could it be possible to use the information, if we explicitly include a disclaimer?
Something in line with: *"It should be noted that the methodology used for the*

quantification of cancer risk for NPC (Nasopharyngeal Cancer), has not been formalised and should not be seen as the official position of the EPA. From a scientific viewpoint, however, we consider this approach as valid and use unit risk to derive the Maximum Permissible Risk (MPR)."

We also noted that in 2014 US-EPA convened a workshop (https://www.epa.gov/sites/production/files/2014-12/documents/formaldehyde_workshop_agenda_final.pdf), the topics of which were the endogenous formation of formaldehyde and its relation to formaldehyde toxicity and the mechanistic evidence for lymphohematopoietic cancer induction by formaldehyde. Any further information on these topics and on the envisaged timeline for finalization of the US-EPA IRIS evaluation would be very welcome.

Maybe we can first do the exchange via mail and decide later on if a telephone conference is useful.

Kind regards

Lidka

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From: "Kraft, Andrew" <Kraft.Andrew@epa.gov>
To: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>,
Cc: Els Smit <els.smit@rivm.nl>, Paul Janssen <paul.janssen@rivm.nl>, "Joke Herremans" <joke.herremans@rivm.nl>, "Glenn, Barbara" <Glenn.Barbara@epa.gov>, "D'Amico, Louis" <DAmico.Louis@epa.gov>, "Bussard, David" <Bussard.David@epa.gov>, "Thayer, Kris" <thayer.kris@epa.gov>
Date: 09/08/2017 05:21 PM
Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Hi Lidka,

Barbara (Glenn) and I are the current chemical managers of the formaldehyde assessment. We were hoping we might be able to set up a phone conversation to talk through the current status of the assessment and your questions below? If so, I can send out some type of Google poll or similar to find a time that works for everyone who might want to participate?

I would emphasize to you that the draft you mention was never finalized after it was released for the purposes of peer consultation and review. Thus, it should not be cited as an EPA position. We can explain this in greater detail when we talk.

We look forward to future conversations,
Andrew and Barbara

From: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>
Sent: Tuesday, August 29, 2017 7:59 AM
To: Kraft, Andrew
Cc: Els Smit; Paul Janssen; Joke Herremans
Subject: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Dr Kraft,
My name is Lidka Maslankiewicz and I work at the Dutch National Institute for Public Health and the Environment (RIVM). We are currently busy with the update of the Maximum Permissible Risk (MPR) for formaldehyde. We would like to use the approach and values described in IRIS Toxicological Review of Formaldehyde (Inhalation) (External Review Draft 2010), in particular Volume 3: "Quantitative Assessment, Major Conclusions in the Characterization of Hazard and Dose Response" (https://cfpub.epa.gov/ncea/iris_drafts/recorddisplay.cfm?deid=223614), to derive MPR value for the Netherlands. Could you, please, inform me, if this could be permitted? Are there more recent versions of this document? If we would be allowed to use your data, how we could refer to the source?

IRIS Toxicological Review of Formaldehyde (Inhalation ...
cfpub.epa.gov

EPA announces the release of the Toxicological Review of Formaldehyde-Inhalation Assessment in the June 2, 2010 Federal Register Notice. This draft assessment is ...

Kind regards

Lidka

Lidka Maslankiewicz

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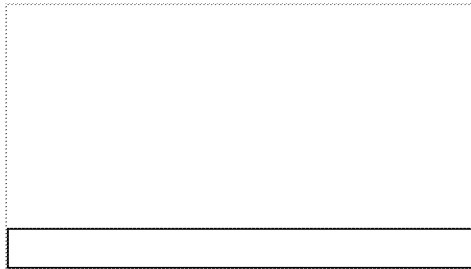
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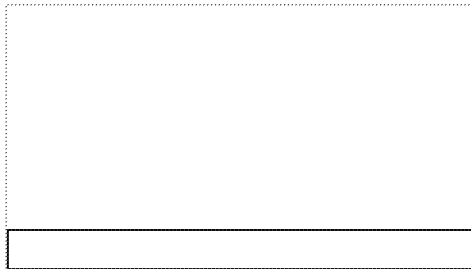
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